UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,405	10/12/2004	Peter Stewart Weisner	PZ0219	9921

36335 7590 03/17/2008

GE HEALTHCARE, INC.
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
MASKELL, MICHAEL P	
ART UNIT	PAPER NUMBER
2881	
MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,405	WEISNER ET AL.	
	Examiner	Art Unit	
	MICHAEL MASKELL	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Strecker, et al (U.S. Patent 3,898,044).

Regarding claim 1, Strecker discloses a device for producing a fluid containing a radioactive constituent, the device comprising a shielded chamber (14) with an opening for receiving an isotope container housing a radioactive isotope; a chamber closure adapted for cooperating with and closing the chamber opening (unlabeled, indicated by reverse cross-hatching relative to side components of chamber 14 in Figs. 1 and 7); a first fluid port comprising a first hollow needle (15 in Fig. 7) projecting into the shielded chamber from the chamber closure for fluid communication with the isotope container; a second fluid port comprising a second hollow needle (15 in Fig. 1) projecting into the shielded chamber from the closed end of the chamber opposite the chamber closure for fluid communication with the isotope container; first and second compressible buffers mounted so as to surround at least partially the respective first and second hollow needles (column 3, lines 3-5), each buffer providing an outer surface for contact with opposed ends of the isotope container; and a spacer of a predetermined thickness associated with one or each of the first and second compressible buffers for

determining the positioning of the isotope container within the shielded chamber (darker cross-hatching in Fig. 7).

Regarding claim 2, Strecker discloses a device as claimed in claim 1, wherein with the chamber closure in place in the chamber opening, the first and second hollow needles are fixed in position at each end of the shielded chamber (Fig. 1).

Regarding claim 3, Strecker discloses a device as claimed in claim 1, wherein the spacer is provided with the second compressible buffer at the closed end of the shielded chamber (Fig. 1).

Regarding claim 6, Strecker's invention is a radioisotope generator.

Regarding claim 7, Strecker discloses a device as claimed in claim 1, wherein opposing ends of the isotope container each includes a frangible seal adapted to be pierced by and to seal around the respective first and second hollow needles (column 3, lines 3-5).

Regarding claim 8, Strecker discloses a device as claimed in claim 1, wherein the isotope container is an ion exchange column (column 2, lines 6-8).

Regarding claim 9, Strecker discloses a device as claimed in claim 1, wherein the first and second hollow needles are each connected via associated fluid conduits (12 and 17a) with a fluid inlet and a fluid outlet respectively.

Regarding claim 10, Strecker discloses a device as claimed in claim 9, wherein the fluid inlet and the fluid outlet each consists of hollow spikes (3 and 18).

Regarding claim 11, Strecker discloses a device as claimed in claim 10 wherein the device further includes an outer housing (33) within which the shielded chamber is

located wherein the fluid inlet and the fluid outlet are mounted in the outer housing to provide fluid connections external to the outer housing (opening through which 17a and 12 are fed in housing 33).

Regarding claim 12, Strecker discloses a device as claimed in claim 11, wherein the fluid conduits each consist of flexible tubing which is greater in length than the distance between the hollow needles and their respective fluid inlet or outlet (12 and 17a are greater than the distance between the needles and the inlet and outlet).

Regarding claim 13, Strecker discloses a device as claimed in claim 12, wherein the flexible tubing of each fluid conduit is in length at least twice the distance between the hollow needles and their respective fluid inlet or outlet (in Fig. 1 12 and 17a can be visually seen to be twice as long as the distance between their respective needles and the opening).

Regarding claim 14, Strecker discloses a method of constructing a radioisotope generator comprising the steps of: providing a shielded chamber (14) with an opening and a chamber closure adapted for cooperating with and closing the chamber opening (unlabeled, indicated by reverse cross-hatching relative to side components of chamber 14 in Figs. 1 and 7); providing a first fluid port comprising a first hollow needle (15 in Fig. 7) projecting into the shielded chamber from the chamber closure; providing a second fluid port comprising a second hollow needle (15 in Fig. 1) projecting into the shielded chamber at the end of the chamber opposite the opening; mounting first and second compressible buffers so as to surround at least partially the respective first and second hollow needles (column 3, lines 3-5), one or each of the compressible buffers including

a spacer of predetermined thickness (darker cross-hatching in Fig. 7); thereafter introducing an isotope container (13) housing a radioactive isotope through the chamber opening into the shielded chamber so as to contact with the second hollow needle and the second compressible buffer at the closed end of the chamber; and closing the shielded chamber by positioning the chamber closure in the opening and bringing the first hollow needle and the first compressible buffer into contact with the isotope container whereby the spacer determines the positioning of the isotope container within the shielded container (Fig. 1).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker in view of Lu, et al ("Characterization of close-celled cellular aluminum alloys" Journal of Materials Science 36(2001) 2773-2786.).

Strecker discloses the device of claim 1, but fails to teach wherein the material of the first and second compressible buffers is a semi-open cell foam. However, Lu teaches that a semi-open cell foam exhibits highly linear stress versus strain behavior compared with closed cell foam when compressed along the X1 direction (Fig. 7). Thus a properly oriented semi-open cell foam behaves elastically under stress. Since the buffer as claimed is intended to be compressible, elastic material is ideal (see Fig. 8a of Lu, where the elastic behavior allows the material to compress without breaking). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use a semi-open cell foam as the material of the first and second compressible buffers. Doing so would allow the buffers to be compressed without breaking.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker in view of Homer, et al (U.S. Patent 4,582,638).

Strecker discloses the device of claim 1, but fails to teach wherein the material of the spacer is a closed cell foam. However, Homer teaches the use of closed cell foam as a gasket in a radioactive material container (column 8, lines 51-60). Homer teaches that such a material is resilient and fluidtight, and prevent damaging loads from being imposed upon a nozzle and tube similar to the needle and tube applied in the present invention. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use closed cell foam as the material of the spacer. Doing so would provide a fluidtight seal and protect the needle and tube from damaging loads.

6. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker.

Regarding claim 15, Strecker discloses the method of claim 14, further comprising the step of connecting the first hollow needle to a first fluid conduit and connecting the second hollow needle to a second fluid conduit, but fails to explicitly teach doing this prior to introduction of the isotope container into the shielded chamber. However, since access to the isotope container is very limited once it is introduced into the shielded chamber, common sense would dictate the connection of the needles to the fluid conduits prior to introducing the isotope container into the shielded chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made to do so, because it would be much easier to access the needles for attachment.

Regarding claim 16, Strecker teaches the method as claimed in claim 15, further comprising the step of locating the shielded container within an outer housing and connecting the first fluid conduit to a fluid inlet in the outer housing and the second fluid conduit to a fluid outlet in the outer housing (see Fig. 1), but fails to teach doing this prior to introduction of the isotope container into the shielded container. However, since the isotope container is radioactive (hence the need for the shielded container), it is much safer to locate the shielded container in the outer housing and connect the fluid conduits before the introduction of the radioactive isotope container. Common sense and ordinary skill in the art would have made it obvious at the time the invention was made to locate the shielded container within an outer housing and connecting the fluid conduits prior to the introduction of the isotope container.

Regarding claim 17, Strecker teaches the method as claimed in claim 16, wherein the first and second fluid conduits are each of flexible tubing which is greater in length than the distance between the first and second hollow needles and their respective fluid inlet and fluid outlet when the chamber closure is in place in the chamber opening and the shielded chamber is positioned within the outer housing (see Fig. 1), but fails to specifically teach whereby all fluid connections can be established prior to installation of the isotope container within the shielded chamber. However, as stated in regards to claim 16, common sense and safety practice would dictate that the introduction of the isotope container within the shielded chamber should only take place after the entire apparatus has been assembled. It would have therefore been obvious to one of ordinary skill in the art at the time the invention was made to establish all fluid connections prior to installation of the isotope container within the shielded chamber. Doing so is the safest way of assembling the apparatus.

Response to Arguments

1. Applicant's arguments filed 02/05/2008 have been fully considered but they are not persuasive. The applicant has argued that Strecker fails to anticipate claim 1 because of an alleged failure to teach that the device described therein comprises compressible buffers; however, as indicated in the previous office action, said compressible buffers are described in column 3, lines 3-5 of Strecker, which reads "The junctions of nuclide generator 13 are provided with piercable stoppers made of an elastic material." Elastic material is compressible, therefore these stoppers are compressible. These stoppers are not represented by the darker cross-hatching in Fig.

7, but rather by the rounded end piece that closes the isotope container just beneath the darker cross-hatching in Fig. 7. The applicant then argues that the compressible buffers in Strecker are not mounted about the needles. Since the needles in Strecker are intended to pierce these stoppers, the stoppers are mounted about the needles once assembly is complete. Finally, the applicant argues that Strecker does not disclose a spacer as defined by claim 1; however, that spacer is what the darker cross-hatching of Strecker's Fig. 7 represents.

2. In regards to claim 14, the applicant claims that Strecker does not teach mounting buffers to the needles as taught and claimed by the present invention. The examiner submits that, by piercing the needles through the buffers as Strecker teaches as described in the rejection of claim 1 and associated argumentation, the buffers come to be mounted to the needles. The applicant further argues that Strecker does not teach a method of constructing a radioisotope generator wherein compressible buffers are required in the construction; however, compressible buffers are called for in the form of "piercable stoppers made of an elastic material." Also, since Strecker's teachings are intended to allow one of ordinary skill in the art to make and use his apparatus, the method of constructing the radioisotope generator taught by Strecker is inherently taught to include all limitations anticipated by Strecker's disclosed apparatus.

3. The applicant's response to the obviousness rejections of the previous office action is based on the alleged failure of Strecker to anticipate claims 1 and 14. Since Strecker does anticipate these claims, the applicant's arguments in re the obviousness rejections under 35 U.S.C. 103(a) are unpersuasive.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MASKELL whose telephone number is (571)270-3210. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571/272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Maskell/
Examiner, Art Unit 2881
01 March 2008

/ROBERT KIM/

Supervisory Patent Examiner, Art Unit 2881